

SHIPPED: Between 1-2-58 and 7-8-58, from Chicago, Ill., by Chicago Pharmacal Co.

RESULTS OF INVESTIGATION: Analysis showed that the article contained pyrogens.

LIBELED: 9-9-58, N. Dist. Calif.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for *Congo red injection* set forth in the United States Pharmacopeia.

DISPOSITION: 11-5-58. Default—destruction.

5791. *Lynnofol* and liver injection. (F.D.C. No. 42293. S. Nos. 35-141/2 P.)

QUANTITY: 47 cartoned vials of *Lynnofol*, and 98 cartoned vials of *liver injection*, at Camden, N.J.

SHIPPED: 6-23-58, from Philadelphia, Pa.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Vial LYNNOFOL (Folic Acid with Liver Liquid)" and "30 cc. Multiple Dose Vial Liver Injection U.S.P. Beef."

RESULTS OF INVESTIGATION: Examination showed that the articles contained not more than 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 11-13-58, Dist. N.J.

CHARGE: 501(b)—the strength of the *liver injection*, while held for sale, differed from the official standard for *liver injection* set forth in the United States Pharmacopeia since the potency of the article was less than that stated on its label; 501(c)—the strength of the *Lynnofol*, while held for sale, differed from that which it purported and was represented to possess, namely, vitamin B₁₂ activity per cubic centimeter equivalent to 20 micrograms cyanocobalamin; and 502(a)—the label statements (*Lynnofol*) "Each cc. contains: * * * Vitamin B₁₂ activity per cc equivalent to 20 micrograms cyanocobalamin" and (*liver injection*) "Vitamin B₁₂ activity p. cc equivalent to 10 micrograms cyanocobalamin" were false and misleading as applied to products which contained less than the stated amount of vitamin B₁₂.

DISPOSITION: 12-22-58. Default—destruction.

5792. Clinical thermometers (oral). (F.D.C. No. 40438. S. No. 23-988 M.)

INFORMATION FILED: 3-18-59, S. Dist. N.Y., against Philbern Thermometer Co., Inc., Bronx, N.Y., and Chester Berns, president.

SHIPPED: 3-30-56, from New York to California.

CHARGE: 501(c)—the thermometers were represented to comply with the requirements of Commercial Standard CS1-52, issued by the National Bureau of Standards of the Department of Commerce, whereas the quality of the thermometers fell below that which they were represented to possess; and 502(a)—the labeling of the thermometers was false and misleading since the thermometers were not accurate within 2/10 of a degree at the degrees of temperature designated in the labeling.

PLEA: Guilty.

DISPOSITION: 6-17-59. Corporation—\$2 fine; individual—\$200 fine, 3 months suspended jail sentence, and probation for 48 hours.

5793. Clinical thermometers (oral). (F.D.C. No. 41699. S. No. 38-894 P.)

QUANTITY: 98 thermometers individually boxed at San Francisco, Calif.

SHIPPED: 12-11-57, from Watertown, N.Y., by Faichney Instrument Corp.

LABEL IN PART: (Box) "Oral Type Fever Thermometer Faichney's Signal Thermometer," (etched on thermometer) "Conn G. Faichney Watertown, N.Y."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Accuracy."

RESULTS OF INVESTIGATION: Examination of 18 thermometers showed that 3 failed to meet the standard of accuracy specified in CS1-52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1-52.

LIBELED: 5-13-58, N. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it did not give accurate readings.

DISPOSITION: 2-27-59. Default—destruction.

5794. Rubber prophylactics. (F.D.C. No. 42242. S. Nos. 22-291 P, 22-293 P, 22-295/7 P.)

QUANTITY: 7 ctns., containing a total of 346 gross; 3 drums, containing a total of 1,000 gross; 9 drums, containing a total of 3,000 gross; and 17 drums, containing a total of 5,666 gross, at Kansas City, Mo.

SHIPPED: Between 7-1-58 and 10-2-58, from Carolina, Puerto Rico, by De Caribe Rubber Co.

RESULTS OF INVESTIGATION: Examination showed that from 1.3 to 2 percent of the article was defective in that it contained holes.

LIBELED: 10-23-58, W. Dist. Mo.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess.

DISPOSITION: The M & M Rubber Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered on 11-21-58, and the article was ordered released under bond for salvaging under the supervision of the Food and Drug Administration. It appearing impractical to process the 7-carton lot, and, the claimant having consented, a supplemental decree was entered on 11-25-58, ordering the article in the 7-carton lot destroyed.

Thereafter, the articles in the drums were retested and the unfit portion was destroyed.

DRUGS FOR VETERINARY USE

5795. Blue Seal All-Mash Grow and Lay Medicated. (F.D.C. No. 42210. S. No. 7-964 P.)

QUANTITY: 80 100-lb. bags at Jonesboro, Maine.

SHIPPED: 8-26-58, from Richford, Vt., by H. K. Webster Co.

LABEL IN PART: "Blue Seal All-Mash Grow and Lay Medicated * * * Active Drug Ingredient: Glycarbylamide (4,5-imidazoledicarboxamide) 0.002% * * * Manufactured by H. K. Webster Company Lawrence, Mass. 6602 Richford, Vermont."

LIBELED: 10-1-58, Dist. Maine.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which is purported and was represented to possess since the article contained sulfaquinoxaline in place of glycarbylamide; 502(a)—the label statement